

Appl. No. : **10/004,522**
Filed : **November 1, 2001**

In the claims:

- 1-19 (Withdrawn)
20. (Original) A particulate coformulation of an active substance and an additive, which is a solid dispersion of one component in the other, but which has a finite gradient in the relative additive concentration, which concentration increases radially outwards from the core to the surface of the particles.
21. (Original) A particulate coformulation according to claim 20, the particles of which have an additive-rich surface region but do not possess separate core and coating layers with a distinct physical boundary between them.
22. (Original) A particulate coformulation according to claim 20, wherein the rate of change in additive concentration, across the particle radius, is continuous rather than stepped.
23. (Original) A particulate coformulation according to any claim 20, wherein the active substance:additive ratio, at the particle surfaces, is sufficiently low for the additive to form, effectively, a protective surface layer around the active substance.
24. (Original) A particulate coformulation according to claim 20, wherein the additive is a taste and/or odour masking agent, and wherein the active substance:additive weight ratio, at the particle surfaces, is sufficiently low for there to be no detectable release of the active substance for at least 30 seconds after the coformulation comes into contact with saliva in a consumer's mouth.
25. (Original) A particulate coformulation according to claim 20, wherein the particle surfaces contain, at their outer limits, no exposed active substance.
26. (Original) A particulate coformulation according to claim 20, which is or comprises a pharmaceutical or nutraceutical agent or a foodstuff.
27. (Original) A particulate coformulation according to claim 20, wherein the additive is an oligomeric or polymeric material.

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28. (Original) A particulate coformulation according to claim 20, wherein the additive is a substance capable of protecting the active substance from external effects such as heat, light, moisture, oxygen or chemical contaminants, and/or of reducing incompatibilities between the active substance and another material with which it needs to be processed or stored, and/or of delaying, slowing or targetting the release of the active substance, and/or of masking the flavour and/or odour of the active substance, when applied to the surface of the active substance.
29. (Original) A particulate coformulation according to claim 28, wherein the additive is a taste and/or odour masking agent.
30. (Original) A particulate coformulation according to claim 20, wherein the active substance comprises a pharmaceutically active substance.
31. (Original) A particulate coformulation according to claim 30, wherein both the active substance and the additive comprise pharmaceutically active substances for co-administration.
32. (Original) A particulate coformulation according to claim 20, wherein the active substance is a carrier, diluent or bulking agent for the additive.
33. (Original) A particulate coformulation according to claim 20, wherein the active substance is present in a crystalline form and the additive is present in an amorphous form.
34. (Original) A particulate coformulation according to claim 33, wherein differential scanning calorimetry (DSC) and/or X-ray diffraction (XRD) analysis of the coformulation indicates reduced active substance crystallinity compared to that of the active substance alone.
35. (Original) A particulate coformulation according to claim 34, wherein the active substance: additive concentration ratio is such that the active substance demonstrates between 20 and 95 % crystallinity as compared to the active substance starting material.
36. (Original) A particulate coformulation according to claim 20, which is in the form of either spherical or approximately spherical particles having a volume mean diameter of between 0.5 and 100 μm , or of needle-like particles having a volume mean length between 5 and 100 μm and a volume mean thickness between 0.5 and 5 μm , or of plate-like particles having a volume mean thickness between 0.5 and 5 μm .

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37. (Original) A particulate coformulation according to claim 20, wherein the active substance concentration is 70 % w/w or greater.
38. (Original) A particulate coformulation according claim 37, wherein the active substance concentration is 80 % w/w or greater.
39. (Original) A particulate coformulation according to claim 20, wherein the additive concentration is 10.
40. (Withdrawn)
41. (Original) A pharmaceutical composition which includes a coformulation according to any one of claims 20 to 39.
42. (Original) A foodstuff or nutraceutical composition which includes a coformulation according to any one of claims 20 to 39.